



Randomised Trial of Flush Saphenofemoral Ligation for Primary Great Saphenous Varicose Veins[☆]

R.J. Winterborn^{a,*}, C. Foy^b, B.P. Heather^a, J.J. Earnshaw^a

^a Department of Vascular Surgery, Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN, UK

^b Research and Development Support Unit, Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN, UK

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KEYWORDS

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Abstract *Objectives:* The aim of this study was to assess different techniques of saphenofemoral ligation in the treatment of primary varicose veins.

Methods: One hundred and eighty-two patients (210 legs) with primary saphenofemoral junction incompetence were randomised to standard saphenofemoral ligation (transfixion with an absorbable suture) (SSL) or flush saphenofemoral ligation (oversewing with 4/0 polypropylene) (FSL). All legs underwent additional great saphenous vein stripping and multiple phlebectomies. Patients underwent assessment preoperatively, and at 6 weeks, 1 year and 2 years postoperatively with clinical examination, duplex imaging and completion of the Aberdeen Varicose Vein Symptom Severity Score (AVVSSS).

Results: A total of 148 patients (172 legs) attended follow-up at 2 years postoperatively. Recurrent varicose veins were visible in 30 legs (33 per cent) in the SSL group and 26 legs (32 per cent) in the FSL group ($P = 0.90$). Neovascularisation was present in 20 groins (22 per cent) in the SSL group and 15 groins (19 per cent) in the FSL group ($P = 0.57$). Nine cases of neovascularisation in the SSL group and five in the FSL group directly resulted in clinical recurrence ($P = 0.37$).

Conclusions: Flush ligation of the saphenofemoral junction confers no advantage over standard ligation with respect to clinical recurrence and neovascularisation.

Registration number: ISRCTN20235689 (<http://www.controlled-trials.com>).

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Introduction

Surgery in the form of saphenofemoral ligation (SFL), great saphenous vein (GSV) stripping and multiple phlebectomies remains the gold standard treatment for primary great saphenous varicose veins. Unfortunately, recurrence rates remain high, despite attempts to improve outcomes by

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* Corresponding author. Miss R.J. Winterborn, Specialist Registrar in Vascular Surgery, 29 Monk Road, Bishopston, Bristol BS7 8LE, United Kingdom. Tel.: +08454 226190; fax: +08454 225683.

E-mail address: becsjazz@tiscali.co.uk (R.J. Winterborn).

ensuring that procedures are performed by appropriately trained surgeons.¹ The majority of research aimed at decreasing recurrence has concentrated on the role of stripping the GSV.^{2–5} Previous research from this institution has shown that whilst stripping the GSV reduces the rate of early recurrence the long-term rate of recurrence is the same.¹ The duplex-findings from this study also revealed that the majority of recurrence was secondary to neovascularisation at the saphenofemoral junction (SFJ).⁶ A number of theories have been postulated to explain the phenomenon of neovascularisation including the idea that hypoxia-induced activation of the vascular endothelial cells lining the residual saphenofemoral stump may stimulate angiogenesis by the release of growth factors.^{7–9}

Standard transfixion ligation of the SFJ leaves a funnel of tissue which is lined by endothelium and therefore may act as a stimulus to new vessel growth. (Fig. 1) An alternative technique is to oversew the SFJ as close as possible to the common femoral vein (CFV), therefore decreasing the amount of exposed endothelium. (Fig. 2)

The aim of this randomised trial was to determine whether the surgical technique employed affected the outcome with respect to rates of recurrence and neovascularisation at 2 years postoperatively.

Methods

Study design

The study was a prospective, randomised, single-blinded trial conducted by a single surgical team at Gloucestershire Royal Hospital, United Kingdom, between February 2003 and November 2004. The study was approved by the Local Hospital Ethics Committee.

All patients assessed in the surgical outpatient department and listed for primary SFL, GSV stripping and multiple phlebectomies were eligible to take part in the study. Those with concomitant saphenopopliteal disease were excluded. Eligible patients were sent a study information leaflet, consent form and disease-specific quality of life questionnaire (Aberdeen Varicose Vein Symptom Severity Score (AVVSS)). Patients were invited to return a completed consent form and AVVSS if they were willing to take part in the study. All study participants underwent pre-operative venous duplex imaging.

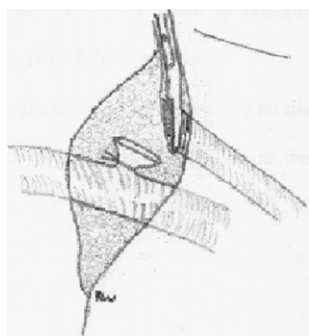


Fig. 1 Diagram showing standard transfixion saphenofemoral ligation.

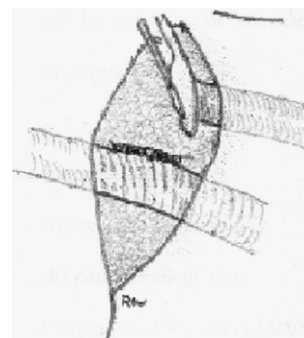


Fig. 2 Diagram showing flush saphenofemoral ligation.

Study population

Between February 2003 and November 2004, 304 legs in 260 patients met the inclusion criteria. One-hundred and eighty-two patients (210 legs) agreed to participate and gave their written, informed consent. Ninety-five patients (114 legs) were randomised to standard saphenofemoral ligation (SSL), and 87 patients (96 legs) were randomised to flush saphenofemoral ligation (FSL). Patient characteristics are shown in Table 1.

Randomisation and blinding

Randomisation was performed using sealed envelopes and the random number generator with varying block sizes in SPSS version 11.5. Envelopes were opened on, or as close as possible to the day of surgery. It was not possible to open all envelopes on the day of surgery as some procedures were performed at peripheral hospitals and the co-ordinator was not always available on the day of surgery to open the next

Table 1 Patient characteristics

	Standard saphenofemoral ligation group (SSL)	Flush saphenofemoral ligation group (FSL)
Patients (n)	95	87
Legs (n)	114	96
Bilateral surgery	19	9
Age, mean \pm SD	47.3 \pm 12.3	52.6 \pm 14.4
Female: Male	69:26	56:31
Right leg: Left leg	52:62	45:52
Pre-operative CEAP class 2	55	53
Pre-operative CEAP class 3	23	11
Pre-operative CEAP class 4	21	17
Pre-operative CEAP class 5	4	5
Pre-operative CEAP class 6	8	8
Pre-operative CEAP class not documented	3	2

Table 2 Grade of first operator performing procedure

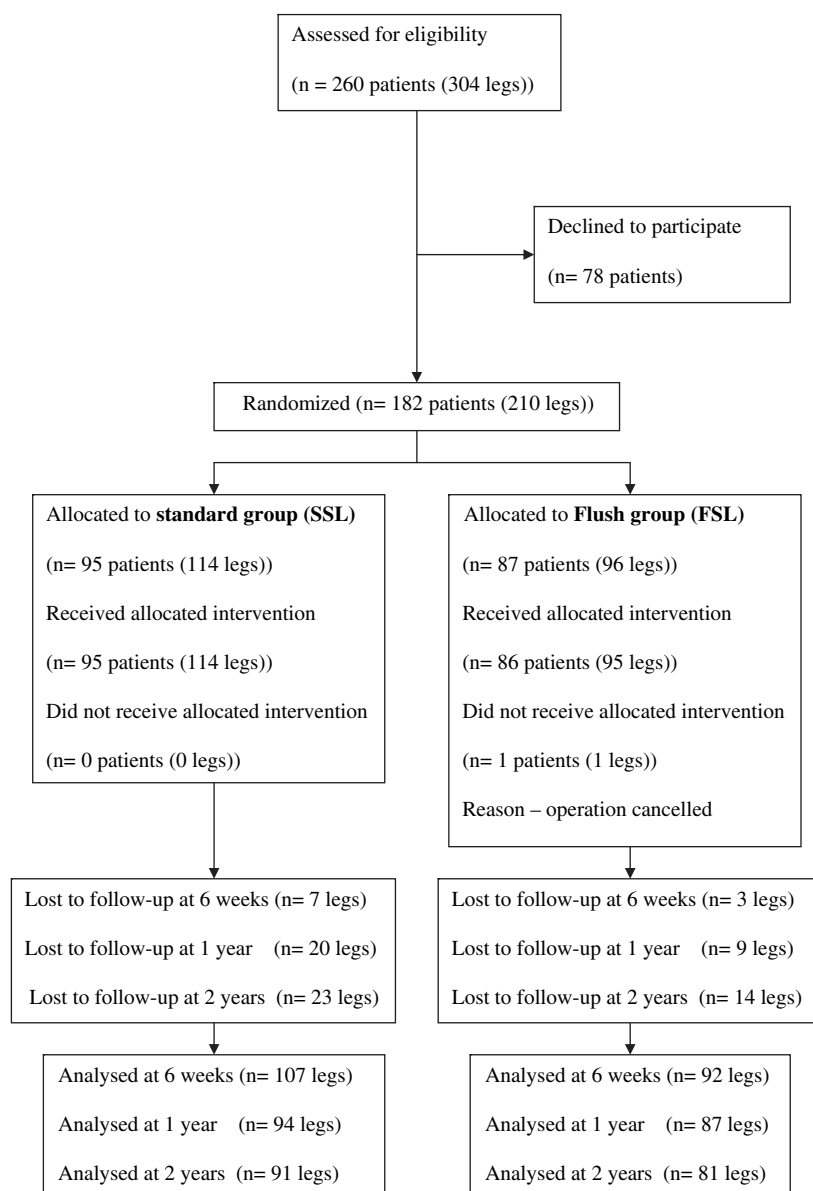
	Standard saphenofemoral ligation group (SSL)	Flush saphenofemoral ligation group (FSL)
Consultant Surgeon	33	20
Associate Specialist Surgeon	20	12
Specialist Registrar	49	52
Senior House Officer	8	6
Missing data	4	5

Chi-squared test, $P = 0.31$.

envelope. Patients rather than individual legs were randomised; therefore those with bilateral varicose veins had the same procedure performed on both legs. Both the patient and the clinician performing the postoperative clinical assessments and duplex imaging were blinded to the surgical technique performed.

Venous duplex imaging

Duplex imaging was performed by a trained technologist using an ATL HDI 5000 colour duplex scanner with a 4–7 MHz linear array transducer. Patients underwent scanning in a sitting position with their legs dependent. Reflux of greater than one second after manual calf compression was taken to signify incompetence. Valsava's manoeuvre was performed if no reflux was detected with calf compression. A whole-leg duplex scan was undertaken with

**Fig. 3** Flow of patients through trial.

documentation of any reflux in the deep and superficial veins. All named vessels and their variants were assessed and varicosities mapped. Neovascularisation was defined as the presence of serpentine venous tributaries entering the CFV at the site of the old SFJ after calf compression or Valsava's manoeuvre. A clinical grading system was used to describe the degree of neovascularisation.

Grade 0: no neovascularisation.

Grade 1: <3 mm diameter vessels.

Grade 2: >3 mm diameter vessels with visible reflux.

No comment was consistently made on the size of the tributaries. Incompetent perforating veins were defined as those with bi-directional flow on calf compression. In general it was not possible to determine the surgical technique performed.

Surgical technique

All operations were performed under general anaesthesia by a trained surgeon. Table 2 shows the number of operations performed by each grade of surgeon for each group ($P = 0.31$).

Patients undergoing bilateral leg surgery and those with risk factors for thromboembolic disease received 20 mg Enoxaparin subcutaneously perioperatively. Surgical technique involved standard exposure of the SFJ with adequate exposure of the CFV (approximately 2–3 cm). All tributaries were diathermy avulsed, at least back to their first division. SSL involved dividing the GSV between haemostats as close as possible to the CFV. The stump was transfixed using a 3/0 polyglycolic acid suture. FSL was performed by placing a C-clamp at the origin of the GSV and dividing it, leaving a small cuff which was oversewn with 4/0 polypropylene. An attempt was made to strip the GSV using a perforate invaginate (PIN) stripper in all cases. Large anterior accessory saphenous veins were also stripped. Remaining tributaries were avulsed using Oesch hooks or fine mosquito forceps.

Postoperative assessment and follow-up examination

All study patients underwent assessment at 6 weeks, 1 year and 2 years postoperatively with clinical examination and venous duplex imaging. Complications of surgery were documented at the 6-week visit and patients were asked to comment on their degree of satisfaction with the surgical outcome at each follow-up appointment. Recurrent varicose veins were defined as any new visible varicosity on clinical examination at 1 and 2 years postoperatively.

Outcome measures

The primary outcome measure was clinical recurrence (any new visible varicosity) at 2 years post-operatively. The secondary outcome measure was the presence of neovascularisation at the SFJ at 2 years post-operatively. Comparisons were also made between the groups with regard to grades of neovascularisation, neovascularisation connecting to vessels in the thigh and neovascularisation causing recurrent varicose veins. Tertiary outcome

measures included complication rates, patient satisfaction, and quality of life data.

Statistical analysis

Sample size was calculated on the basis of the primary outcome measure. Previous research from this centre has shown clinical recurrence rates of 25 per cent at 2 years following SSL and GSV stripping. Data regarding recurrence rates following oversewing of the junction are scarce. The expected clinical recurrence rate for FSL was therefore set at 10%. An enrolment of 98 legs in each group was therefore required to achieve a 5% two-tailed probability of a type I error and a 20% probability of a type II error.

Clinical data were compared using the Chi-squared test and AVVSSS scores were compared using paired and unpaired t-tests. $P < 0.05$ was considered statistically significant.

Results

Between April 2003 and November 2004, 114 legs in 95 patients underwent standard saphenofemoral ligation (SSL) and 95 legs in 86 patients underwent flush saphenofemoral ligation (FSL). Fig. 3 shows the flow of patients through the study. Successful SFL was documented for all patients. The degree to which the GSV was successfully stripped is shown in Table 3; there was no statistically significant difference between the groups ($P = 0.51$).

6-week follow-up

Eighty-nine patients (107 legs) in the SSL group and 79 patients (92 legs) in the FSL group attended early follow-up. One patient withdrew from the study for personal reasons and the remainder were lost to follow-up. Twelve legs in the SSL group and 2 in the FSL group reported groin wound infections ($P = 0.01$). A total of 4 legs developed a groin haematoma, 3 in the FSL group ($P = 0.24$). Three legs developed a seroma, 2 in the FSL group ($P = 0.47$). Twenty-three legs (21 per cent) in the SSL group and 27 legs (29 per cent) in the FSL group developed cutaneous

Table 3 Level to which GSV was stripped

	Standard saphenofemoral ligation group (SSL)	Flush saphenofemoral ligation group (FSL)
GSV stripped to just below knee	67	50
GSV stripped to knee	21	24
GSV stripped to just above knee	11	13
GSV reverse stripped	1	1
Failed to strip	10	2
GSV – multiple phlebectomies only		

Chi-squared test, $P = 0.51$.

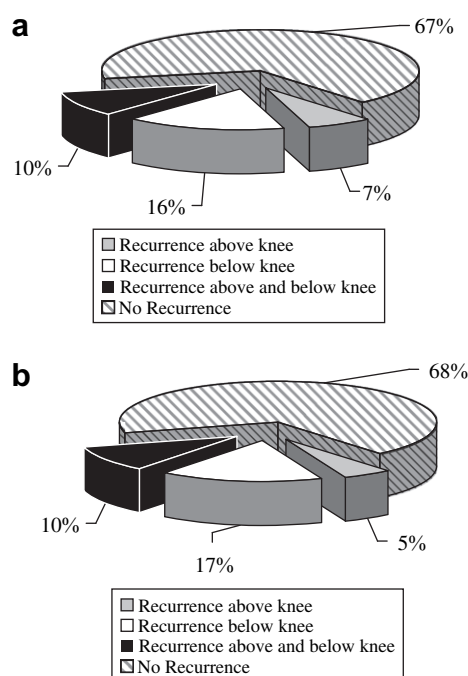


Fig. 4 (a). Recurrence rates for standard saphenofemoral ligation group. (b). Recurrence rates for flush saphenofemoral ligation group.

numbness ($P = 0.60$). Two patients in the SSL group developed a below knee deep vein thrombosis (DVT) and a further patient had a non-fatal pulmonary embolism; one of the patients who developed a DVT did not receive peri-operative thromboprophylaxis as they were considered to be low-risk. One patient in the FSL group had a non-fatal peri-operative myocardial infarction. Nineteen legs (18 per cent) in the SSL group and 24 legs (26 per cent) in the FSL group had residual varicose veins either above or below or the knee, at 6-week follow-up ($P = 0.21$). Seventy-eight patients, 89 legs in the SSL group (83 per cent) and 81 patients, 85 legs in the FSL group (92 per cent) were happy with the results of surgery ($P = 0.14$). Four patients, 4 legs in the SSL group and 2 patients, 2 legs in the FSL group were not happy with the results of surgery. The remainder were neither happy nor unhappy with the result. Quality control duplex imaging revealed a total of 5 legs in the SSL group and 1 leg in the FSL group in which the SFJ remained present ($P = 0.14$). In 1 leg in the SSL group and 1 leg in

the FSL group it remained present and incompetent, representing a failure to identify the SFJ correctly. In the remaining 4 legs the SFJ was competent pre and post-operatively, however, there was still a failure to identify and ligate the SFJ.

1-year follow up

Seventy-nine patients (94 legs) in the SSL group and 75 patients (87 legs) in the FSL group attended follow-up at 1 year postoperatively. Three patients (4 legs) had moved away from the area, 1 patient (2 legs) died of unrelated causes, 1 patient had already withdrawn and the remainder were lost to follow-up. Seven legs in the SSL group and 11 legs in the FSL group had ongoing cutaneous numbness ($P = 0.24$). Residual varicose veins remained visible in 5 legs (5 per cent) in the SSL group and 10 legs (11 per cent) in the FSL group ($P = 0.29$). Recurrent varicose veins had developed and were visible in 19 legs (20 per cent) in the SSL group and 10 legs (11 per cent) in the FSL group ($P = 0.11$). Thigh varicosities were visible in 5 legs (5 per cent) in the SSL group, but only one leg (1 per cent) in the FSL group ($P = 0.13$).

Duplex imaging showed groin neovascularisation in 20 legs (21 per cent) in the SSL group, and 12 legs (14 per cent) in the FSL group ($P = 0.08$). The neovascularisation connected to a thigh vessel in 7 legs (7 per cent) in the SSL group and 3 legs (3 per cent) in the FSL group ($P = 0.24$). This led to clinical recurrence in 4 legs (4 per cent) and 2 legs (2 per cent) respectively ($P = 0.46$). Seventy-two patients, 82 legs in the SSL group (87 per cent), 73 patients, 80 legs in the FSL group (92 per cent) ($P = 0.29$) remained happy with the results of surgery.

2-year follow-up

Seventy-five patients (91 legs) in the SSL group and 73 patients (81 legs) in the FSL group attended follow-up at 2 years postoperatively. The reasons for failure to attend follow-up were as documented at 1-year postoperatively. Recurrent varicose veins were visible in 30 legs (33 per cent) in the SSL group (Fig. 4a) and 26 legs (32 per cent) in the FSL group ($P = 0.90$). (Fig. 4b) Neovascularisation was present in 20 legs (22 per cent) in the SSL group and 15 legs (19 per cent) in the FSL group ($P = 0.57$). Table 4 shows grades of neovascularisation and connection with a thigh vein. Neovascularisation was the cause of

Table 4 Grades of neovascularisation and connection with thigh vein at 2-year follow-up

	Standard saphenofemoral ligation group (SSL)	Flush saphenofemoral ligation group (FSL)	<i>P</i> value*
No neovascularisation (Grade 0)	71	66	$P = 0.26$
Neovascularisation < 3 mm (Grade 1)	5	3	$P = 0.57$
Neovascularisation > 3 mm (Grade 2)	15	12	$P = 0.76$
Neovascularisation > 3 mm connecting to competent thigh vein	4	0	$P = 0.06$
Neovascularisation > 3 mm connecting to incompetent thigh vein	9	5	$P = 0.37$
Neovascularisation > 3 mm connecting to incompetent thigh vein causing recurrence	9	5	$P = 0.37$

*Chi-squared test.

Table 5 Comparison of quality of life scores

	Standard saphenofemoral ligation group (Mean with S.D.)	Flush saphenofemoral ligation group (Mean with SD)	<i>P</i> value*
Mean Preoperative AVVSSS	19.15 S.D. 10.60	18.33 S.D. 10.11	
Mean 6-week AVVSSS	9.93 S.D. 9.70	7.55 S.D. 6.87	<i>P</i> = 0.07
Mean 1-year AVVSSS	6.78 S.D. 7.32	6.25 S.D. 5.73	<i>P</i> = 0.62
Mean 2-year AVVSSS	8.42 S.D. 9.21	8.83 S.D. 8.24	<i>P</i> = 0.78

*Comparison of means at each follow-up point using unpaired t-test.

recurrence in 9 legs (10 per cent) in the SSL group and 5 legs (6 per cent) in the FSL group (*P* = 0.37).

The degree of patient satisfaction remained 87 per cent for the SSL group but decreased to 78 per cent for the FSL group (*P* = 0.40). No patients underwent treatment for recurrent varicose veins during the study period.

Quality of life analysis

There was no statistically significant difference in AVVSSS between the SSL group and the FSL group at any time point. (Table 5) There was a statistically significant improvement in AVSSS at 6 weeks, 1 year and 2 years following surgery for both groups (*P* < 0.001).

Conclusions

The surgical treatment of varicose veins has changed very little over the last century. Many studies have explored the importance of stripping the GSV with a wide range of reported recurrence rates (7 to 65 per cent).^{3,5,6,10,11} Studies from this institution have shown no difference in long-term recurrence, but a reduction in re-operation rates with routine stripping.¹ A number of centres have studied the use of barrier techniques in the search for a method of decreasing recurrence secondary to neovascularisation.^{12–15} Gibbs used a reflected flap of pectineus fascia and showed no difference in re-recurrence rates in patients with recurrent varicose veins.¹⁶ A number of different synthetic materials have been used including silicone patches and polytetrafluoroethylene (PTFE) patches. De Maeseneer showed lower rates of neovascularisation in patients who had a silicone patch inserted over the ligated SFJ.^{13,14} In our institution we have explored the use of PTFE patches. Whilst the pilot studies showed promising results a randomised trial of patients with recurrent varicose veins showed no improvement in the rates of neovascularisation.^{17,18}

Few have studied different techniques of performing the SFL itself. There have been reports of using microclips rather than suture material¹⁹ and of leaving a long stump in order that the walls of the funnel of GSV flop together, decreasing the amount of exposed endothelium.²⁰ The only randomised trial of different ligation techniques was performed by Frings *et al.* They randomised 500 legs into different operative groups. Groups A and B underwent SFL with an absorbable 0 Vicryl® suture. Groups C and D underwent SFL with a non-absorbable Ethibond® suture. In addition, a continuous Prolene® was sutured over the stump in groups B and D. Unfortunately, only 152 legs were followed up at 2 years postoperatively. Whilst the rates of

neovascularisation were low (3 legs, 0 legs, 5 legs and 2 legs respectively), statistical analysis showed no difference in the rate of recurrent saphenofemoral incompetence.²¹ Jaeschok also studied this technique but the follow-up interval was only 3 months.²²

This study is the first to compare standard transfixion ligation with oversewing of the junction, flush with the CFV. The strengths of this study are that it is a randomised, single-blinded trial with 2-year follow-up involving clinical examination and detailed duplex imaging. As has been the case in previous studies on patients with varicose veins those requiring bilateral surgery had the same procedure performed on both legs. This helps to account for the difference in numbers of legs between the groups. The number of patients attending follow-up at each time point was reasonable although we should have allowed for a larger drop out rate when calculating the numbers required. The catchment area for Gloucestershire Royal Hospital is wide and therefore many patients had to travel significant distances to attend follow-up appointments.

The 6-week follow-up served to assess complication rates and allow quality control of the surgery by duplex imaging. The rates of infection were high; however, these were patient reported infections. The difference between the two groups was statistically significant (*P* = 0.01). Perhaps more attention was paid to meticulous haemostasis in those patients who underwent oversewing of the junction, alternatively it could be related to the fact that the absorbable suture was braided and the non-absorbable suture was a monofilament. One could argue, with this rate of infection, that all patients having SFL should receive a dose of perioperative antibiotics. The rising rate of hospital-acquired infections, however, is a strong argument against this. The rate of numbness was similar to previous studies.^{23–25} The remaining complications are a consequence of the volume of cases performed and serve as a reminder that varicose vein surgery does occasionally result in complications. The number of legs with residual varicose veins at 6 weeks was surprisingly high (22 per cent), although the majority were below the knee and many disappeared by one-year postoperatively (1-year rate, 8 per cent). The most striking finding at 6 weeks was the rate of surgical failures. Much emphasis is placed on the importance of the grade and experience of the surgeon performing the procedure, however, there were 6 legs in which there was failure to accurately identify the SFJ. Three were performed by a consultant and 3 by a Specialist Registrar. In 4 legs an incompetent anterior thigh vein was stripped rather than the GSV. The junction left behind was competent in all cases. In 2 legs a GSV tributary was removed and in 1 leg there was ongoing

saphenofemoral incompetence. Interestingly 5 of the 6 failures were in the standard surgery group; this may be accounted for by the fact that in order to perform flush ligation the surgeon has to expose the junction more clearly in order to be able to manoeuvre the C-clamp into position.

The primary outcome measure was clinical recurrence at 2 years postoperatively. At 1 year the rate of recurrence in the standard group was 20 per cent and in the flush group it was 11 per cent. Whilst the difference was 9 per cent it was not statistically significantly different ($P = 0.11$). At 2 years the difference between the groups dropped to less than 1 per cent. Even comparing recurrence above the knee there was no difference. The results cannot be explained by the drop off in follow-up as of those that did not attend, 2 in each group had visible vessels in the thigh at 1 year and none had neovascularisation, therefore it is unlikely that there would have been more recurrences in the standard group than the flush group. With regard to the rate of neovascularisation, the overall difference approached significance at 1 year, however, at 2 years there was no difference. Breaking down the groups into grades of neovascularisation, there was a statistically significant difference for grade 2 neovascularisation at 1 year ($P = 0.03$); however, this had disappeared by 2 years.

The theory behind this study was that the residual saphenofemoral stump somehow stimulates neovascularisation. As described in the introduction, it has been suggested that hypoxia-induced activation of endothelial cells distal to the stump ligation may encourage new vessel growth.^{7,26,27} By performing a flush ligation not only is the stump removed but an attempt is made to invert the edges during oversewing in order to decrease the area of exposed endothelium. This randomised study shows that there is no reduction in the rate of recurrence or neovascularisation by performing a flush ligation.

The advent of endovascular techniques and the lack of associated neovascularisation would suggest that groin dissection and ligation do play a role, however, haematoma in the strip-track may also be a factor,²⁸ which is removed by performing one of the new techniques.

Surgery remains the most commonly performed procedure for varicose veins, despite the high rates of recurrent varicose veins.²⁹ Proponents of radiofrequency ablation, endovenous laser treatment and foam sclerotherapy cite the ability to perform these techniques in an outpatient setting under local anaesthetic as a reason to consider switching from conventional surgery. There is, however, no long-term data on clinical outcomes, although some authors suggest that there is less post-operative pain and a faster return to work with radiofrequency ablation.³⁰

There has been a significant amount of research into different techniques for decreasing neovascularisation. The results of this study were not positive in favour of oversewing the SFJ. The findings serve to close the chapter on attempts at novel methods of ligation and stripping.

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